This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information. Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-F-0001

CUSTOMER NO. 962

FORM APPROVED OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

See Attached Listing

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

U.S. ENVIRONMENTAL PROTECTION AGENCY NATIONAL HEALTH & ENVIRONMENTAL

RESEARCH LAB (MAIL DROP 51) RESEARCH TRIANGLE PA. NC 27711 (919) 541-2281

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional FACILITY LOCATIONS(sites)

				sary or use APHIS FORM 7023A)	
A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	TOTAL NO. OF ANIMALS (Cols. C+ D+E)
4. Dogs	None	None	None	None	0
5. Cats	11	17	11		0
6. Guinea Pigs	ff	6	11	11	6
7. Hamsters	11	5	11	"	5
8. Rabbits	**	13		11	13
9. Non-Human Primates	None	None	11	11	0
10. Sheep	None	None	11	11	0
11. Pigs					
12. Other Farm Animals					
13. Other Animals		*			
······					
		1			

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION	BY HEADQUARTERS RESEARCH FACILITY OFFICIAL	
• • • • • • • • • • • • • • • • • • • •	e Officer or Legally Responsible Institutional official) above is true, correct, and complete (7 U.S.C. Section 2143)	
SIGNATURE OF C.F.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		11-30-04

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-F-0007
CUSTOMER NUMBER: 955

FORM APPROVED OMB NO. 0579-0038

\_\_\_\_\_

JOINT SPECIAL OPERATIONS MEDICAL TRAINING

ANNUAL REPORT OF RESEARCH FACILITY

USAJFKS
RIDG 5-

CENTER
USAJFKSWCS
BLDG 5-3845

OCT 2 2 2004

KEDENBURG STREET

FORT BRAGG, NORTH CAROLINA 28310-5200

Telephone- (910)396-0089

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS L	JSEL	BY OR UNDER C	:ONT	ROL OF RESEAR	CH F	ACILITY ( Attach additional	she	eets if necessarv or use APHIS Form 7023A )	
A. Animals Covered By The Animal Welfare Regulations		Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C.	Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	which experiments, teaching, research, surgery or tests were conducted accompanying pain or distress to the anim the use of appropriate anesthetic, analges drugs would have adversely affected the producing accompanying pain or distress to the animals an for which appropriate research, surgery or tests were conducted accompanying pain or distress to the animal the use of appropriate anesthetic, analges drugs would have adversely affected the producing of the teaching, research, surgery or tests were conducted accompanying pain or distress to the animal the use of appropriate anesthetic, analges or interpretation of the teaching, research, surgery or tests were conducted accompanying pain or distress to the animal the use of appropriate anesthetic, analges or interpretation of the teaching, research, surgery or tests were conducted accompanying pain or distress to the animal surgery.		Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquilizings would have adversely affected the procedures, resor interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )	
4. Dogs									
5. Cats									
6. Guinea Pigs									
7. Hamsters									
8. Rabbits									
9. Non-human Primates									
10. Sheep									
11. Pigs						8			8
12. Other Farm Animals									
GOATS						2716			2716
13. Other Animals		· · · · · · · · · · · · · · · · · · ·			T				
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#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reset teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incoming brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

ending veterinarian for this research racinty has appropriate authority to ensure the provision of abequate veterinary care and to oversee the adequacy of other aspects	or arminar care and doc.
CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )	
NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED

See attached form for

Interagency Report Control No.:

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

UNITED STATES DEPARTMENT OF AGRICULTURE

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

additional information

1. CERTIFICATE NUMBER; 55-R-0001

CUSTOMER NUMBER: 825

FORM APPROVED OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Wake Forest University Medical Center Boulevard Winston Salem, NC 27109

Telephone: (336) -716-4548

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

Bowman Gray Campus (001) <u>Friedberg Campus (003)</u>

FACILITY LOCATIONS (Sites) - See Atached Listing

Reynolda Campus

(004)

Chestnut Campus

(005)

REPORT OF ANIMALS	USED BY OR UNDER (	CONTROL OF RESEAR	al sheets if necessary or use APHIS Form 7023A )		
A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whith the use of appropriate anesthetic, analgesic, or tranquilizings would have adversely affected the procedures, resorinterpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs		0	69	0	69
5. Cats		0	89	0	89
6. Guinea Pigs		0	0	0	0
7. Hamsters		0	0	0	0
8. Rabbits		0	104	0	104
9. Non-human Primates		207	1,089	22	1,318
10. Sheep		77	186	0	263
11. Pigs		45	79	29	153
12. Other Farm Animals					
13. Other Animals					
Squirrels		48	0	0	48
Bats	<u>-</u>	36	0	0	36
Ferrets		129	5	0	134

#### **ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures
- This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL. (Type of Print)

DATE SIGNED

Cin

# Attachment to APHIS FORM 7023 Summary of Exceptions to Regulations and Standards Wake Forest University 55-R-0001 Fiscal Year 2003-2004

1. The following is an exception to the requirements for sanitizing nonhuman primate primary enclosures at required frequencies:

Building 02 on the Friedberg Campus is used to house nonhuman primates imported directly from foreign sources (Indonesia). As required by the Centers for Disease Control (CDC), cages used in this building can not be sent through the mechanical cage washer until after the first thirty-one days (Phase I) of quarantine. Animal waste is removed from cage pans daily. After monkeys have completed Phase I quarantine, cages are sanitized at intervals in accordance with federal regulations and standards.

2. The following protocol involves an exception to the AWA regulation limiting animals to one protocol with a major survival operative procedure. The exception involves an iliac artery biopsy, performed via laparotomy, in 45 animals transferred from a previously approved protocol in which an ovariectomy had been done 4-5 years prior. The ovariectomized monkeys were uniquely suited to the current study, designed to investigate the cardiovasular health benefits of estrogen treatments in early vs late menopause, which is a question of importance to women's health. The purpose of the iliac artery biopsy was to establish the characteristics of atherosclerosis at baseline for subsequent evaluations. A written request was made to and approved by the Deputy Administrator, Animal Care, APHIS, USDA, on September 23, 2004.

A04-105: Comparison of the Effects of Estradiol and Equol on Cardiovascular Risk Factors and Atherosclerosis of Surgically Postmenopausal Cynomolgus Monkeys

Species Used: Female cynolmolgus monkeys (Macaca fascicularis)

Number Used: 45

- 3. All of the following protocols involve exceptions to the cage size requirements for sheep primary enclosures. Each exception was approved by the Wake Forest University (WFU) Animal Care and Use Committee (ACUC), after their determination of scientific justification. For each protocol listed, sheep (Ovis aries) are used in studies of pituitary-adrenal hormones, renin, and vasopressin, and are housed in metabolism carts for up to fourteen days. These studies are important to the understanding of factors relating to the health and survival of newborn infants. The Committee's justification for the exception is based on data that show movement of animals in and out of the carts on a daily basis would adversely influence the hormones measured in these experiments.
  - a. A01-079: Fetal Endocrine-Cardiovascular Relationships Number Used: 50
  - b. A02-099: Vulnerability of the Fetal Brain to Hypoxia-Ischemia Number Used: 12
  - c. A02-196: Prenatal and Neonatal Pituitary-Adrenal Function Number Used: 42
  - d. A03-009: Local Control of the Fetal Renin-Angiotensin System Number Used: 17

e. A03-148: Prenatal Glucocorticoid and Postnatal Blood Pressure Number Used: 117

- 4. The following protocols involve exceptions to the requirements for watering nonhuman primates. For each protocol listed, full access to water is regulated in a manner to ensure animals are adequately motivated to perform traditional operant conditioning paradigms. Each exception was approved by the WFU ACUC, after their determination of scientific justification.
  - a. A03-075: Diencephalic Mechanisms of Visuomotor Integration

Access to water is regulated such that the first fluid intake of the day will occur during a training or experimental session. A well-trained animal will work to satiety during an experimental session and, in doing so, obtain its minimum daily water requirement. In the event that the animal does not obtain its minimum fluid intake during a session, fluid will be supplemented to the appropriate level when the animal is returned to its home cage. Typically, water regulation is begun on Sunday in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday morning. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed daily (on the days they are tested). Health and hydration are assessed every day by both research and veterinary personnel. These studies are important to understanding the neural bases of sensory and motor control of the mechanisms of decision making in humans.

Species Used: Male rhesus monkeys (Macaca mulatta)

Number Used: 4

# b. A04-050: Cortical Implications for Rehabilitation

Access to water is regulated such that the first fluid intake of the day will occur during a training or experimental session. A well-trained animal will work to satiety during an experimental session and, in doing so, obtain its minimum daily water requirement. In the event that the animal does not obtain its minimum fluid intake during a session, fluid will be supplemented to the appropriate level when the animal is returned to its home cage. Typically, water regulation is begun on Sunday in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday morning. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed daily (on the days they are tested). Health and hydration are assessed every day by both research and veterinary personnel. Findings from this study will aid in improving rehabilitive therapy for individuals following a stroke.

Species Used: Male rhesus monkeys (Macaca mulatta)

Number Used: 4

## c. A02-135: Cross-Modal Integration in Primate Midbrain

Water regulation only occurs during periods of training and experimentation. Throughout the year animals are given ad lib access to water for variable, but often extended periods of time (months). Prior to initiation of training, each animal's ad lib intake of fluid is measured each day to determine its normal daily fluid consumption; generally this is between 200-250 ml. Then, during training and experiments, the animal is allowed to work to satiety during a session. If the animal will not work for that long, which can occur particularly early in the training, its fluid intake is supplemented with either pieces of fruit (apple, orange) or Gatorade. On the weekends, each animal is given access to water ad lib in its cage. A daily

requirement. In the event that an animal does not obtain its minimum intake during a session (particularly during the early stages of training) it is supplemented after the end of the session by the investigator.

Animals participate in experiments 5 days a week and have first firs

during an experimental session and, in doing so, obtain its minimum daily water requirement (as determined by a formula based on age, size and weight of the animal). In the event that the animal does not obtain its minimum fluid intake during a session, or does not perform a session on a given day, fluid is supplemented to the appropriate level via a water bottle placed on the home cage. Typically, water regulation is begun on Sunday afternoon in preparation for behavioral testing on Monday. Animals participate in experiments on Monday through Friday and receive ad libitum access to water on Friday afternoon through Sunday afternoon. Throughout the duration of an individual animal's participation in experimental protocols, fluid intake, weight, and a variety of other physiological and behavioral measures are recorded to assure the animal's continued health and well-being. Animals are weighed on the days they are tested (or at least weekly). Health and hydration are assessed every day by both research and veterinary personnel.

One of the aims of this study is to identify those brain areas and types of cognitive behaviors most affected by brief (36-54 hour) sleep deprivation in an animal model. A monkey performs its behavioral/recording session normally during the day before sleep deprivation. That evening, before the lights go off in the housing area, the monkey is moved to a separate room in which the lights stay on all night and is kept awake by use of nonaversive stimuli (videos, music, food treats, toys, random computer sounds, interactions with technicians). Monkeys that fall asleep are reawakened within 5-10 minutes. The behavioral and electrophysiological testing of the monkey is then repeated the following afternoon. When possible, two monkeys are sleep deprived at a time, and are housed in single cages facing each other to maintain social contact throughout the night. Sleep deprivation studies are performed at minimum 10 day intervals, typically only once per 2-4 weeks per monkey. Information from these studies will aid understanding of human brain function and suggest means to combat sleep deficiences.

Species Used: Male rhesus monkeys (Macaca mulatta)

Number Used: 21

6. The following protocol involves an exception to the lighting and space requirements for cats. The exceptions were approved by the WFU ACUC, after determination of scientific justification.

# A02-042: Experiential Influences on Cross-Modal Development

This study examines the role of visual experience on the development of multisensory processes in the midbrain. From birth, kittens are raised to adulthood in total darkness. Total darkness is required to eliminate all visual experience during development in a reversible manner. Procedures such as enucleation or eyelid-suturing are inadequate because they are not reversible or allow a significant amount of light to penetrate the lids. A portion of the population is returned to full-spectrum lighting at six to twelve months of age. When in darkness, animals are cared for in accordance with all other standards and regulations. Infrared goggles are used by animal care, veterinary, and research personnel who enter the room daily to perform routine husbandry, health evaluations, and research manipulations. Criteria for monitoring the health and well-being of animals were developed, reviewed, and approved by the ACUC. All dark-reared animals have remained healthy and gain weight at rates similar to age-matched controls.

Animals in the room spend six hours per day together in an experimental pen which provides adequate space, but less than the minimum square footage per cat required by the USDA for standard housing. The size of the pen is a critical element in restricting the sensory experience of these animals, since it serves to constrain the minimum and maximum angular disparities of visual and auditory experience. Enlarging the size of the experimental pen would increase the maximal disparity beyond that which is believed to have an effect on reorganization in the nervous system. It is imperative that experimental animals are placed in the pen together to receive the same environmental manipulation. Any difference in the sensory experiences of the animals would constitute an unresolvable confound in the interpretation of the subsequently gathered data. It is important to note that animals are only in the run for six hours per

day, after which they are returned to pens that provide the minimum square footage per cat required by the USDA. Results from this work are important for the improved treatment of children with visual disorders such and blindness, amblyopia, and strabismus.

Species Used: Male and female domestic shorthair cats (Felis domesticus)

Number Used: 37

# Attachment to APHIS FORM 7023 Explanation of Column E Procedures Wake Forest University 55-R-0001 Fiscal Year 2003-2004

The following protocols involve experiments reported in Column E. Experiments were approved by the Wake Forest University (WFU) Animal Care and Use Committee (ACUC), after their determination of scientific justification.

A02-127: Neurophysiological Recording from Nonhuman Primate Brain
 Number of animals used in this study: 22
 Species (common name) of animals used in the study: Male rhesus monkeys (Macaca mulatta)

Explain the procedure producing pain and/or distress:

One of the aims of this study is to identify those brain areas most affected by sleep deprivation in an animal model. To that end, monkeys are kept awake for 36-54 hours by use of nonaversive stimuli (lights, videos, music, food treats, toys, random computer sounds, interactions with technicians). Behavioral, electrophysiological, and brain metabolic parameters measured after deprivation are compared to baseline parameters. Sleep deprivation studies are performed at minimum 10 day intervals, typically only once per 2-4 weeks per monkey. While the procedures used to produce sleep deprivation are not themselves considered painful, it is recognized that the lack of sleep may cause monkeys to experience unrelieved "distress" during the 36-54 hours when they are kept awake. The distress is minimized by using the nonaversive stimuli, constant interaction with technician staff with whom the monkeys are most familiar, maintainance of social interaction by working with two monkeys at a time (in single cases facing each other), and by allowing the monkey to sleep immediately following the testing.

Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see next response.):

Although humans can undergo brief periods with little to no sleep, the problems of extended sleep deprivation are vitally important. This is especially true for military pilots and personnel in combat in this Department of Defense funded study, but also for shift-workers, medical personnel, mothers with very young children, and long-distance truck drivers all of whom must continue to do their essential duties with prolonged periods of sleep loss or interruption. Despite such sleep deprivation, societal and job demands require these individuals to be attentive, remember accurately, and make appropriate decisions. Before an effective means of alleviating the effects of sleep deprivation on memory, attention, and decision-making can be developed, it is necessary to identify those cognitive functions and brain areas most affected by sleep deprivation. This ACUC approved study is necessary to characterize the effects of sleep deprivation in an animal model that is quite similar to that of a human performing a job that requires hand-eye coordination, short-term memory, and decisions based on information presented in the task. The experiment provides access to information (i.e. electrophysiological measures and testing of paliative drugs) that cannot be obtained in human studies. The procedures themselves are not painful, but the actual experience of being sleep-deprived may result in distress to the monkeys, which would be unrelieved during the 36-54 hours that they are kept awake. However, since the stress of sleep deprivation is precisely the effect being studied, it cannot be alleviated during the period of the experiment. Efforts are made to alleviate the distress as soon as the experimental measurements are completed, and sleep deprivation is not repeated for a minimum of 10 days.

What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):

Agency:

CFR:

This experiment is funded by the Defense Advanced Research Projects Agency (DARPA) as part of "Preventing Sleep Deprivation" contract DAAD19-02-1-0060.

2. A04-001: Prostanoids and Hypoxic Neonatal Pulmonary Hypertension Number of animals used in this study: 29
Species (common name) of animals used in the study: Piglet

Explain the procedure producing pain and/or distress:

This experiment examines the effects of low levels of oxygen (hypoxia) on tiny blood vessels from the lungs of newborn pigs. Piglets are placed in a veterinary incubator and a hypoxic atmosphere is provided by delivering 10%  $O_2$  at atmospheric pressure to simulate the environment of newborns born and living at an altitude of 15,000 feet. Control piglets are housed in a similar chamber but with a room air environment. Rapid gas flow and the use of soda lime  $CO_2$  absorbent is used to keep the  $CO_2$  level at approximately 3-5 mm Hg. The temperature and humidity of the chamber is monitored carefully. Each chamber provides sufficient space to meet regulatory requirements. Piglets remain in the incubator under the control or hypoxic environment for 3 days. Both the control and hypoxic chamber are opened approximately 1 to 3 times a day for 30 minutes to one hour to clean the chamber and replenish food. Although animals are not expected to experience significant discomfort, piglets are monitored for difficult breathing and other signs of respiratory distress, and euthanized if such signs are observed.

Provide scientific justification why pain and/or distress could not be relieved. State methods used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see next response.):

Pulmonary hypertension is a well-recognized complication of human infants with a variety of cardiopulmonary disorders. Because the infants are not able to get enough oxygen, they develop structural abnormalities of the blood vessels in the lung which lead to extreme disability and sometimes death. The mechanisms involved in the initiation and maintenance of pulmonary hypertension are not well understood and currently there are few good options for treating these critically ill newborns. The goal of this project is to help understand why infants develop pulmonary hypertension and what goes on in the lungs during development of the disease. Although the procedures used in this experiment were not thought to cause significant pain or distress in animals, the ACUC felt that unavoidable discomfort might be experienced by piglets during the period of hypoxia required to induce pulmonary hypertension (3 days). Any potential discomfort was felt to be scientifically justified since maintaining the piglets in an hypoxic environment is the only known method for replicating the condition seen in human infant

What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):

Agency: Not applicable CFR: Not applicable

See attached form for additional information

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0002
CUSTOMER NUMBER: 861

FOF

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Research Triangle Institute 3040 Cornwallis Rd. P.O. Box 12194 Research Triangle Pa, NC 27709

DEG 01 2004

Telephone: (919) -541-6182

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	3	6	0	9
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	0	0	0	0
7. Hamsters	0	0	0	0	0
8. Rabbits	24	0	187	0	187
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0
					-

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incoming brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

The diterioring retermination time research recently ride appropriate at	and the provided of adolption for the contract of the contract	
	TION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL excutive Officer or Legally Responsible Institutional Official)	
SIGNATURE OF C.F.O. OR INSTITUTIONAL OFFICIAL	MAME & TITLE OF C.E.O. OD INCTITUTIONAL OFFICIAL (Type or Driet)	DATE SIGNED
		11/30/04

W.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to cenalties as provided for in Section 2150.

See reverse side for additional information

Interagency Report Control No. 0180-DOA-AN

result in an order to cease and desist and to be subject to penalties as provided for in Section 2 150		additional information	140. 0 100-DOA-A14
UNITED STATES DEPARTMENT OF AGRICULTURE	1. REGISTRATION NO.	CUSTOMER NO.	FORM APPROVED OMB NO. 0579-0036
ANIMAL AND PLANT HEALTH INSPECTION SERVICE	55-R-0003	863	05/9-0036
ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	HEADQUARTERS RES     USDA, include Zip Code	•	e and Address, as registered with
	DUKE UNIVER	RSITY	
	BOX 3180 DUI	MC	
	DURHAM, NC	27710	
	(919) 681-6792	2	
3. DEDODTING EACH ITY (List all locations where animals were housed or used in actual research	testing or experimentation or	held for these numoses	Attached additional sheets if

REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attached additional sheets if necessary.)

FACILITY LOCATIONS (sites)

See Attached Listing

REPORT OF ANIMALS USE	D BY OR UNDER CON	TROL OF RESEARCH F	ACILITY (Attach additional shee	ts if necessary or use APHIS FORM 7023A)	<del></del>
A.  Animals Covered by the Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, or research or surg. / but not yet und for surpose.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery or tests. (An explanation of procedures producing pain or stress in these animals and the reasons such figs were not used must be attached to to the stress in these.)	F.  TOTAL NO. OF ANIMALS  (Cols. C + D + E)
4. Dogs	2	6	83		89
5. Cats		5	1		6
6. Guinea Pigs		31	280		311
7. Hamsters					
8. Rabbits		176	788		964
9. Non-Human Primates		59	3		62
10. Sheep		8	14		22
11. Pigs	10	8	681		689
12. Other Farm Animals					

Goats	3	2	5
13. Other Animals			
Ferrets	6	65	71
Monodelphis	66		66
Tree Shrew	141		141
Gerbil	1	25	26

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

	care and use.						
	CERTIFICATE OF PRINCIPAL INVESTIGATOR						
at the above is true, correct, and complete (7 U.S.C. Section 2143)							
	SIG		NIANAE & TITLE OF DIOP INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED			
				12/1/04			
	APł	osolete)	PART	1 - HEADQUARTERS			

Interagency Report Control I

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! See attached form for additional information.

ANIMAL AND PLANT HEALTH INSPECTION SERVICE

UNITED STATES DEPARTMENT OF AGRICULTURE

1. CERTIFICATE NUMBER: 55-R-0004

CUSTOMER NUMBER: 826

FORM APPROVED OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY** 

(TYPE OR PRINT)

University Of North Carolina @ Chapel Hill Cb# 7115-B12 Berryhill Hall Div. Of Lab Animal Medicine Chapel Hill, NC 27599

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBEI OF ANIMALS  ( COLUMNS C + D + E
4. Dogs		138	56		194
5. Cats	11	1.6	2		18
6. Guinea Pigs			48		48
7. Hamsters		24			24
8. Rabbits		46	136		182
9. Non-human Primates	12		8		8
I0. Sheep		7	6		13
11. Pigs		85	87		172
12. Other Farm Animals					
13. Other Animals					

# **ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFI	CIAL
( Chief Executive Officer or Legally Responsible Institutional Official	)

INIAME & TITLE OF CEO OD INSTITUTIONAL OFFICIAL / Type or Print

IDATE SIGNED

, which is obsolete.)

# 3. Facility Locations:

- A) Mary Ellen Jones
- B) Thurston-Bowles Building
- C) Dental Research Center
- D) Beard Hall (Closed December 2003)
- E) Davie Hall
- F) Berryhill Hall
- G) Taylor Hall
- H) McGavran-Greenberg
- I) Francis Owen Blood Research Laboratory
- J) Animal Resources Center
- K) Neuroscience Research Center
- L) Molecular Biology Research Lab (Glaxo) (Closed May 2004)
- M) Kerr Building
- N) Medical Biomolecular Research Building

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0005
CUSTOMER NUMBER: 842

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

North Carolina State University Box 8401

Raleigh, NC 27695

Telephone: (919) -513-6280

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, resion interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	10	49	84		134
5. Cats			127	10	13'7
6. Guinea Pigs		17	31		28
7. Hamsters			19		19
8. Rabbits		78	99		177
9. Non-human Primates					<u>'.</u>
0. Sheep		69	38		107
1. Pigs		1:33	4810	180	1,249
2. Other Farm Animals		77	io		\$3
Guats		410	25		71
3. Other Animals					
Herses	2	41	63		104
Pine vole	223	287	31		318
rass hopper Mice		104	<del>                                     </del>		64

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reseteaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and act institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary and brief explanation of the exceptions, as well as the species and number of animals affected.

The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal ca
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	The state of the s	tale and to oversee the adequacy of other aspects	s or animal care and use.
		ADQUARTERS RESEARCH FACILITY OFFICIAL er or Legally Responsible Institutional Official)	
SIGNA		NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ( Type or Print )	IDATE SIGNED
APHIS F	88), which is obsolete.)		



UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

FORM APPROVED OMB NO. 0579-0036

# CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

55- R-0005- OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA NOV TO Clarolina State Liverisity

Bex 8401

Bakish, NC 27695

REPORT OF ANIMALS USED BY OF	UNDER CONTROL OF	F RESEARCH FACILITY	(Attach adicimonal sheets if ne	Cassage or use this form )	<del></del>
A. Animals Covered By The Animal Wetfare Regulations  12. &/OR 13. Other (List by species)	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C Number of animals upon which feaching, research, experiments, or lests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be atteched to this report).	TOTAL NO. OF ANIMALS  (Cois. C + D + E)
Red Wolles			2		ス
Ferrets			12		12
Mardehicks		<u> </u>	4		4
trials	<u> </u>		20		<b>9</b> 0
Pallas! Cats		1	2	5	8
TRESTRINS		43	15		58
	<u> </u>				
		<u></u>			
			<u> </u>		
		<u> </u>			
		<u> </u>			
					-
ASSURANCE STATEMENTS				أعان ومدنوار ووفق اليوران الفاتار والمساول والمساول والمتاوي والمتاوي والمتاوي	ه مستور

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including approxiate use of anesthetic, analgesic, and tranquitizing drings, prior to, drimms, and following actual research, feaching, testing, surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to painful procedures
- 3). This facility is adhering to the standards and regulations usider the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Anenal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4). The affending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of

aninai care and use.		•
C	ERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)  1 certify that the above is true, correct, and complete (7 USC Section 2143)	
SIGN	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL ITYPO OF PRINTY	DATE SIGNED
ABUIS SORM 7002A		

(AUG 91)

# **FACILITY LOCATION FOR USDA REPORT 2004**

Site A: College of Veterinary Medicine

Site A Address: Laboratory Animal Resources (LAR)

Site A City, State, Zip: Raleigh, NC

Site B: College of Veterinary Medicine

Site B Address: Veterinary Equine Research Center (VERC)

Site B City, State, Zip: Southern Pines, NC

Site C: College of Veterinary Medicine

Site C Address: Teaching Animal Unit (TAU)

Site C City, State, Zip: Raleigh, NC

Site D: College of Agriculture and Life Sciences

Site D Address: Biological Resources Facility (BRF)

Site D City, State, Zip: Raleigh, NC

Site E: College of Agriculture and Life Sciences

Site E Address: Lake Wheeler Field Laboratory - Swine

Site E City, State, Zip: Raleigh, NC

# Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Name, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

- 1. Registration Number: 55-R-0005
- 2. Number of animals listed by species (common name) used in this study.

  1 dog
- 3. Explain the procedure producing pain and/or distress. Infection of splenectomized dog with Babesia canis.
- 4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see question 5 below)

Distress caused by reaction to parasites. Dog became inappetent for almost 24 hours; pain not observed.

5. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency	CFR

# Checklist:

- Only the animal numbers used on this one protocol are provided
- □ Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- □ The Category E explanation is completed

# USDA Annual Report

# Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Name, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

- 1. Registration Number: 55-R-0005
- 2. Number of animals listed by species (common name) used in this study. Cats 10
- 3. Explain the procedure producing pain and/or distress.

  Transient physical restraint for 1) collection of feces from the colon using soft plastic, lubricated loop, 2) collection of venous blood or 3) collection of urine by bladder centesis.

Cats were infected orally with <u>T. foetus</u>. This resulted in a transient diarrhea that has completely resolved. There are presently no clinical signs of <u>T. foetus</u> infection.

4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results ( For Federally mandated testing, see question 5 below)

The only discomfort not relieved is that associated with the transient diarrhea. The reason for this is that there is presented no specific or symptomatic therapy capable of ameliorating diarrhea in cats infected with <u>T. foetus</u>.

5. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency _	N/A	CFR	N/A

#### Checklist:

- Only the animal numbers used on this one protocol are provided
- □ Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- □ The Category E explanation is completed

# Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Name, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

			•	
2.	Number of animals listed by species (common name)	used in	this	study.
	12 pigs			

3. Explain the procedure producing pain and/or distress.

1. Registration Number: 55-R-0005

We orally administer Salmonella to pigs, then collect fecal samples over time to assess carriage and shedding. To study the effects of various mutations in Salmonella genes on animal carriage, we administer mutant bacteria in combination with their wild type equivalents to determine whether the mutants fail to survive in the pig intestinal tract. To study the effects of the intestinal environment itself on Salmonella survival, we alter the pigs' diet in ways that are likely to change the intestinal milieu, than test the survival of Salmonella in the intestinal tract.

Pigs are very resistant to salmonellosis. In most cases, we observe no clinical signs after infection with *Salmonella*. Some pigs do become pyrexic, can be lethargic, and can have diarrhea (occasionally with blood). These signs, when they do occur, are generally mild and resolve without treatment in 1-2 days.

4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see question 5 below)

The goal of this work is expressly not to make animals sick, so that we can study the long-term asymptomatic carriage of Salmonella. When animals do show clinical signs of salmonellosis, there are no effective treatments that would ameliorate those signs without altering the course of the disease. Administration of antibiotics might reduce the signs, but clearly these would also affect the test results.

5.	What, if any, Federal regulations require this procedure?	Cite	the
	agency, the Code of Federal Regulations (CFR) title number	and	the
	specific section number (e.g., APHIS, 9 CFR 113.102):		

AgencyCFR	Agency	CFR
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# USDA Annual Report

# Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. Name, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

- 1. Registration Number: 55-R-0005
- 2. Number of animals listed by species (common name) used in this study. 10 pigs
- 3. Explain the procedure producing pain and/or distress. Animals were exposed to skin carcinogens (DMBA and MNNG) for 6 months on a weekly basis. Skin changes were observed and samples (skin punches) collected at 10 week intervals.
- 4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results ( For Federally mandated testing, see question 5 below) It would not have been possible or beneficial to maintain the animals under analgesics for 6 months as the distress shown by the animals was minimal.
- 5. What, if any, Federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency: Aphis CFR: 9CFR, Part 2, Section 2.36

#### Checklist:

- Only the animal numbers used on this one protocol are provided
- Each animal is only counted once
- The numbers are entered in the columns, which correlate to the protocol
- ☐ The Category E explanation is complete

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-R-0007 CUSTOMER NO. 829

FORM APPROVED OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

UNC @ CHARLOTTE CHARLOTTE, NC 28223-0001 . HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

UNIVERSITY OF NORTH CAROLINA

UNIVERSITY OF NORTH CAROLINA 9201 UNIVERSITY CITY BLVD. CHARLOTTE, NC 28223

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS(sites)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals	<u> </u>				
		·			
	1				1

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  (Chief Executive Officer or Legally Responsible Institutional official)  I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)					
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	11/24/2004			
1					

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

**PART 1 - HEADQUARTERS** 

NOV 1 7 2004

See attached form for additional information. Interagency Report Con

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0010 **CUSTOMER NUMBER:** 

819

FORM APPROVED OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY** 

(TYPE OR PRINT)

**East Carolina University** Department Of Comparative Med, **School Of Medicine** Greenville, NC 27858

Telephone: -(940): 946-2979

(252)744-2420

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered  By The Animal  Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs			36		36
5. Cats					
6. Guinea Pigs	23		35		58
7. Hamsters					
8. Rabbits			50		50
9. Non-human Primates			19		19
10. Sheep					
11. Pigs			147		147
12. Other Farm Animals					
13. Other Animals					
Ferret			10		10

#### ASSURANCE STATEMENTS

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reteaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

		EADQUARTERS RESEARCH FACILITY OFFICIAL per or Legally Responsible Institutional Official )	
SIGNATU .		NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
APHIS FO	ich is obsolete.)		

( AUG

# FACILITY SITES LISTING

censee/Registrant Name: <u>E</u>	East Carolina University
cense/Registration Number:	55-R-0010
<u>.</u>	
clude all requested information	ouse regulated animals under the above number. Be sure to on. If the line does not apply, please mark it N/A. If you have his form as many times as needed before filling in the sites.
ite No.: 1 Name/Departme	ent: School of Medicine
Addre	ss: Moye Boulevard, East Carolina University
	Greenville, NC 27858
Buildi	ng: Brody Medical Sciences
Floor/Ro	om: Animal Housing on Ground and Seventh Floor; Research
	Laboratories on Floors Three thru Eight
Contact Pers	son: Phone No.:
Site No.: 2 Name/Departm	nent: School of Medicine
Addı	ress: Emergency Drive, East Carolina University
	Greenville, NC 27858
Build	ling: Life Sciences Building
Floor/Re	oom: Animal Housing on First Floor; Research Laboratories
	on Second Floor

# FACILITY SITES LISTING

icensee/Registrant Name:	East Carolina University	
License/Registration Number:	55-R-0010	
include all requested informat	house regulated animals under the above number. Be sure to ion. If the line does not apply, please mark it N/A. If you have this form as many times as needed before filling in the sites.	
•		
Site No.: 3 Name/Departm	ent: Biology	
Addr	ess: East Carolina University	·
	Greenville, NC 27858	
Build	ling: Howell Science Complex	
Floor/R	oom: First and Third Floors – Animal Housing Facility	
Contact Per		
Site No.: 4 Name/Depart	ment: Psychology	
	lress: East Carolina University	•
· · ·	Greenville, NC 27858	
Bui	lding: Ragsdale and Ragsdale Annex	
Floor/I	Room: First Floor – Animal Housing Facility and Laboratories	
Contact Pe		

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER:

CUSTOMER NUMBER:

55-R-0012 820 FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University Of North Carolina @ Wilmington 601 South College Rd. Wilmington, NC 28403 NOV 3 0 2004

Telephone: (910) -962-3810

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS	USED BY OR UNDER (	CONTROL OF RESEAR	CH FACILITY ( Attach additiona	al sheets if necessarv or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted invoiving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					``
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Prairie Vole	197	84	0	0	84
ASSURANCE STATEMENTS	3				

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reset teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incident brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

		CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )		
٤	HAL	THANE & TITLE OF O E O OD INSTITUTIONAL OFFICIAL / Time or Drink )	DATE SIGNED	
			11-24-04	
A	23 (OCT 88), which is obsole	ete.)		

See attached form for additional information. Interagency Report Contr

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0012

CUSTOMER NUMBER: 820

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University Of North Carolina

@ Wilmington

601 South College Rd. Wilmington, NC 28403

Telephone: (910) -962-3810

DEC 02 2004

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Prairie Vole	197	84	0	0	84
		<del></del>	<del></del>		

#### **ASSURANCE STATEMENTS**

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to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects	
BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  Officer or Legally Responsible Institutional Official )	
NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
	Y HEADQUARTERS RESEARCH FACILITY OFFICIAL Officer or Legally Responsible Institutional Official)

APHIS FORM 7023

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

(AUG 91)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0013

CUSTOMER NUMBER: 821

See attached form for

additional information.

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Greer Laboratories Inc Albion Medical Holdings Inc 639 Nuway Circle, N.E. P.O. Box 800 Lenoir, NC 28645

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS	REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )				
A.  Animale Covered By The Animal Welfare Regulations	B. Number of enimal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animats upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquilized rugs would have adversely affected the procedures, resor interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animats and the reast such drugs were not used must be attached to this report.)	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS
4. Dogs					
5. Cats					
6. Guinea Pigs	514	3,596			3,596
7. Hamsters					
8. Rabbits	8		4		4
9: Non-human Primates					
10. Sheep					
11.º Pigs					
12. Other Farm Animals					
13. Other Animals					

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of enestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rescreecing, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and applicational Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incident brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinaries for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other espects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL (Chief Executive Officer or Legally Responsible Institutional Official)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

APHIS FORM 7023

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

(AUG 91)

See attached form for additional information.

Interagency Report Control

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0017
CUSTOMER NUMBER: 822

FORM APPROVED OMB NO. 0579-0036

UCT 1 8 2004

# ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Ciit Centers For Health Research 6 Davis Drive

Research Triangle Pa, NC 27709

Telephone: (999)-999-9999 919-558-1200

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yε used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquilitz drugs would have alversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
·		Only lab	oratory mice and	rats which are exempt from	
		regulation	on under the AWA	were utilized during this	
		reportin	g period.		

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

	DQUARTERS RESEARCH FACILITY OFFICIAL or Legally Responsible Institutional Official)	
	NAME & TITLE OF C. F.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
		10/15/04

See attached form for additional information. Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

\* This report is required by law (7 USC 2143). Failure to report according to the regulations can

result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

1. CERTIFICATE NUMBER: 55-R-0019 CUSTOMER NUMBER:

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)

Central Carolina Community College 1105 Kelly Drive Sanford, NC 27330

862

Telephone: (919) -775-5401

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS (	JSED BY OR UNDER C	ONTROL OF RESEAR	CH FACILITY ( Attach addition	al sheets if necessary or use APHIS Form 7023A )	<del></del>
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	OF ANIMALS  ( COLUMNS  C + D + E )
4. Dogs	0	0	43	0	43
5. Cats	0	0	35	0	35
6. Guinea Pigs	0	5	0	0	<u>S</u>
7. Hamsters	0	0	0	0	0
8. Rabbits	0	0	12	0	12_
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals		-			
Cows	0	0	5	0	2
13. Other Animals					
Horses	0	0	5	0	5

#### **ASSURANCE STATEMENTS**

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )					
	11	=	DATE SIGNED		
			10-5-04		
	which is obsolete.)				



### LEE COUNTY CAMPUS

1105 Kelly Drive ● Sanford, NC 27330 919-775-5401 ● (FAX) 919-775-1221 SERVING CHATHAM, LEE & HARNETT COUNTIES

Facility Locations (Sites)

1. Small animals: Central Carolina Community Collège Science Building / Vet. Lab

1105 Kelly Drive Sanford, NC 27330

Z. Carge animals: Graster's Farm 2718 Country Way Sanford, NC 27330 See attached form for

Interagency Report C

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

> UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER:

55-R-0021

CUSTOMER NUMBER: 823

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University Of North Carolina

@ Greensboro

Research Services Rm.100 Mciver Bldg

Greensboro, NC 27402

Telephone: (336) -334-5878

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary

EBERHART BUILDING - FIRST FLOOR

FACILITY LOCATIONS (Sites) - See Atached Listing

EBERHART BUILDING - SIKITH FLOOR

STONE BUILDING-FIRST FLOOR

REPORT OF ANIMALS (	USED BY OR UND	ER CONTROL OF RESEAS	RCH FACILITY ( Attach additiona	al sheets if necessarv or use APHIS Form 7023A )	
A.  Animals Covered  By The Animal  Welfare Regulations	B. Number of anin being bred, conditioned, or held for use in teaching, testin experiments, research, or surgery but not used for such purposes.	animals upon which teaching, research, ng, experiments, or tests were conducted	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					Ø
5. Cats					Ø
6. Guinea Pigs					Ø
7. Hamsters					Ø
8. Rabbits					Ø
9. Non-human Primates					Ø
10. Sheep					Ø
11. Pigs				·	Ø
12. Other Farm Animals					Ø
13. Other Animals					Ø

# **ASSURANCE STATEMENTS**

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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CERTIFICATI	ON E	IY HEA	DQUA.	RTERS F	RESEARC	H F/	ACILI	TY OFFICIAL	

( Chief Executive Officer or Legally Responsible Institutional Official )

NAME & TITLE OF OF OR INSTITUTIONAL OFFICIAL (Time of Fried)

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0022

CUSTOMER NUMBER: 813

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

North Carolina A&T State University Lab. Animal Resource Unit 116 Webb Hall Greensboro, NC 27411

NOV 302004

Telephone: (336) -334-7720

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments. research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquility drugs would have adversely affected the procedures, resion interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	TOTAL NUMBE OF ANIMALS ( COLUMNS C + D + E )
4. Dogs	2	1	5	0	6
5. Cats	0	1	0	0	1
6. Guinea Pigs	14	23	15	0	38
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1	0	0	1
9. Non-human Primates	0	0	0	0	0
IO. Sheep	0	0	0	0	0
11. Pigs	0	0	6	0	6
12. Other Farm Animals	_	-	-	-	-
13. Other Animals		_			
Gerbils	26	35	17	0	52
30.5110					

#### ASSURANCE STATEMENTS

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QUARTERS RESEARCH FACILITY OFFICIAL or Legally Responsible Institutional Official)	
NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
	11/29/0

osolete.)

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! See attached form for additional information. Interagency Report Control I

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0027

CUSTOMER NUMBER: 827

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Professional Lab & Research Services 1251 Nc 32 North Corapeake, NC 27926

Telephone: (252) -465-8686

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reask such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	7	498	0	0	498
5. Cats	19	126	0	O	lab
6. Guinea Pigs	Ö	0	0	D	0
7. Hamsters	O	0	0	0	0
8. Rabbits	15	151	0	Ö	151
9. Non-human Primates	0	0	0	0	0
10. Sheep	O	0	0	0	0
11. Pigs	0	O	0	0	0
12. Other Farm Animals	0	_ <u>ک</u>	0	0	٦
13. Other Animals	0	0	0		

#### ASSURANCE STATEMENTS

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		TION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ecutive Officer or Legally Responsible Institutional Official)	
SI	AL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
			23NIN OY

See attached form for additional information. Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0104
CUSTOMER NUMBER: 8210

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

University Of North Carolina-Asheville Cpo #1440 The University Of Nc At Asheville One University Heights Asheville, NC 28804

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS (	USED BY OR UNDER C	ONTROL OF RESEAR	CH FACILITY ( Attach additiona	al sheets if necessarv or use APHIS Form 7023A)	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	Ò	0	0	0
7. Hamsters	D	0	0	0	0
8. Rabbits	0	D	0	6	0
9. Non-human Primates	0	0	0	0	0
10. Sheep		0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	0	0	6	0
13. Other Animals	0	0	0	0	0

#### ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incident brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

SIG	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED

(AUG 91)

T 88), which is obsolete.)

See reverse side for additional information

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-R-0107 CUSTOMER NO. 808

FORM APPROVED OMB NO. 0579-0036

# ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

CAROLINAS MEDICAL CENTER DIRECTOR COMPARATIVE MEDICINE P.O. BOX 32861 CHARLOTTE, NC 28232-2861

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

CAROLINAS MEDICAL CENTER
CHARLOTTE, NC 28232

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquillizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs			21		21
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			35		35
9. Non-Human Primates					
10. Sheep					
11. Pigs			88		88
12. Other Farm Animals					
13. Other Animals					·
Sand Rats	54		75		75
Ferrets			4		4

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

(Chief Executive C	HEADQUARTERS RESEARCH FACILITY OFFICIAL  Officer or Legally Responsible Institutional official)  ove is true, correct, and complete (7 U.S.C. Section 2143)	
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	11/30/2004

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 55-R-0108 CUSTOMER NO. 815

FORM APPROVED OMB NO. 0579-0036

# **ANNUAL REPORT OF RESEARCH FACILITY**

(TYPE OR PRINT)

HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
 INTEGRATED LABORATORY SYSTEMS, INC.

800-12 CAPITOLA DR PO BOX 13501

RESEARCH TRIANGLE PA, NC 27713

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (sites)

INTEGRATED LABORATORY SYSTEMS

DURHAM, NC 27713

REPORT OF ANIMALS USED BY	OR UNDER CONTROL O	F RESEARCH FACILITY	(Attach additional sheets if neces	ssary or use APHIS FORM 7023A)	
A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs			<u> </u>		
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs		<u></u>			
12. Other Farm Animals					
13. Other Animals	<u> </u>				
ASSURANCE STATEMENTS		-			

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all the exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  (Chief Executive Officer or Legally Responsible Institutional official)  I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)				
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED		
		11/09/2004		

## **APHIS Form 7023 Additional Reported Sites**

The following additional sites have been reported by the facility. The reported sites have not been verified by APHIS and have been provided by the facility solely for completeness of the APHIS Form 7023 Annual Reporting submission.

Registration Number:

55-R-0108

**Customer Number:** 

815

Facility:

INTEGRATED LABORATORY SYSTEMS, INC.

800-12 CAPITOLA DR

PO BOX 13501

RESEARCH TRIANGLE PA, NC 27713

Site B Keystone Technical Park Site B 601 Keystone Park Drive, Suite 100 Site B Durham, NC 27713 This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

NUV 1 6 2004

See attached form for additional information.

~ Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0109 CUSTOMER NUMBER: 816

FORM APPROVED OMB NO 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY** (TYPE OR PRINT)

Bayer Corporation, Pharmaceutical Div.

P. O. Box 507 Clayton, NC 27520

Telephone: (919) -553-5011

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS	ORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )							
A.  Animals Covered  By The Animal  Welfare Regulations	B. Number of enimal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which leaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animats upon which experiments, teaching, research, surgery, or lests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquilizings would have adversely affected the procedures, resion interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )			
4. Dogs								
5. Cats					<u> </u>			
6. Guinea Pigs		2456		2574**	5030			
7. Hamsters								
8. Rabbits		2175			2175			
9. Non-human Primates								
10. Stieep								
11. Pigs								
12. Other Farm Animals								
13. Other Animals								
				See attached**				

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquitizing drugs, prior to, during, and following actual rest teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal Investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incoming the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian	for this research facility has appropriate autho	ority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects	of animal care and use.
		N BY HEADQUARTERS RESEARCH FACILITY OFFICIAL tive Officer or Legally Responsible Institutional Official)	
SIGNATURE OF CEOOR INS		NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
APHIS:	3 (OCT 88), which is obs	olete.)	

# Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1.	Registration Number: 55-R-0109
2.	Number 2574 of animals used in this study.
3.	Species (common name) <u>Guinea pigs</u> of animals used in the study.
4.	Explain the procedure producing pain and/or distress.
	a. Diphtheria potency - To determine the anti-diphtheria potency of
	intramuscular and intravenous products using neutralization
	methodology.
	b. Tetanus potency - To quantitate the potency of Tetanus Immune
	Globulin (Human) by using neutralization methodology.
5.	Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)
	This testing is mandated by Bayer Product License Testing Requirements.
	Administration of anesthetic, analgesic or tranquilizer drugs could
	interfere with the outcome of the testing.
6	What if any foderal regulations require this presenting? City the appear the saids of Endard Day (altimos
Ο.	What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):
	Agency FDA CFR 21 CFR 640.100

Customer ID and Site Address:

ID: 816

8368 US 70 West Clayton, NC 27520 County: Johnston Telephone

(919) 553-5011

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21! See attached form for additional information SEP Buerage 2018 ort Control Co

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0111

CUSTOMER NUMBER: 959

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

**Davidson College** P.O. Box 7118 Davidson, NC 28035

Telephone: (704) -894-2617

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS L	REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )						
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS		
4. Dogs							
5. Cats							
6. Guinea Pigs							
7. Hamsters							
8. Rabbits							
9. Non-human Primates							
10. Sheep							
11. Pigs			·				
12. Other Farm Animals							
13. Other Animals							
Gerbils	64	271					
	·						

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

		EADQUARTERS RESEARCH FACILITY OFFICIAL cer or Legally Responsible Institutional Official)	
		NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
<b>-</b>	solete.)		

Interagency Report Control lio.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0114

CUSTOMER NUMBER: 988

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Gaston College/Vet Tech Program 222 Leisure Lane Dallas, NC 28034

NOV 0 9 2004

Telephone: (999) -999-9999

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS (	USED BY OR UNDER		CH FACILITY ( Attach additiona	il sheets if necessarv or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	TOTAL NUMBER OF ANIMALS ( COLUMNS C + D + E )
4. Dogs		50	104	0	154
5. Cats		30	54	0	84
6. Guinea Pigs			400 Nan	0	0
7. Hamsters			. = -	0	Ŏ
8. Rabbits		0	7	0	7
9. Non-human Primates				0	0
10. Sheep				0	0
11. Pigs				0	0
12. Other Farm Animals					
Cattle		5	0	0	5
13. Other Animals					
Horses		5		0	5

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incipief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

	TION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ecutive Officer or Legally Responsible Institutional Official)	
SIGNATURE OF A FO AN INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED

Interagency Report Contro No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0115

CUSTOMER NUMBER: 1638

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Molecular Toxicology, Inc. 157 Industrial Park Dr. Boone, NC 28607

NOV 0 1 2004

Telephone: (828) -264-9099

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS	REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )								
A.  Animals Covered By The Animal Welfare Regulations	B.	Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C.	Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D.	Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E	Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquilizings would have adversely affected the procedures, resor interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs									
5. Cats									
6. Guinea Pigs									
7. Hamsters						770			770
8. Rabbits									
9. Non-human Primates									
10. Sheep									
11. Pigs									
12. Other Farm Animals	-								
13. Other Animals									

## ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reseteaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

The attending Vetermanian for this research leastly has appropriate detailed,		وبالمراكب المستوي والمستوي
	BY HEADQUARTERS RESEARCH FACILITY OFFICIAL c Officer or Legally Responsible Institutional Official)	
CICNATURE OF CEO OR INSTITUTIONAL OFFICIAL	MANUE & TITLE OF OF O OD INSTITUTIONAL OFFICIAL (Time or Print)	DATE SIGNED
		10.29.00

h is obsolete.)

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0117
CUSTOMER NUMBER: 9721

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Icagen, Inc 4222 Emperor Boulevard

Suite 350 Durham, NC 27703

Telephone: (919) -941-5206

NOV 2 22004

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

Suite 460, same address as above.

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )						
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquillzing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, rese or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	OF ANIMALS  ( COLUMNS  C + D + E )	
4. Dogs	Ó	0	O	Ö	. 0	
5. Cats	ට ට	Ò	0	0	0	
6. Guinea Pigs	<b>ට</b>	12	C	Ò	12	
7. Hamsters	0	0	0	0	0	
8. Rabbits	0	0	0	0	0	
9. Non-human Primates	0	0	0	0	0	
10. Sheep	0	O	0	0	O	
11. Pigs	0	0	0	0	0	
12. Other Farm Animals	0	0	0	0	0	
13. Other Animals	0	0	0	0	0	

## ASSURANCE STATEMENTS

(,

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual researching, testing, surgery, or experimentation were followed by this research facility.
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- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

7		
	CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )	
SIGN.	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED   11//6/04
APHIS	:h is obsolete.)	

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0118
CUSTOMER NUMBER: 13918

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Biotechnics 310 Millstone Drive Hillsborough, NC 27278

Telephone: (919) -245-3114

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered  By The Animal  Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs	0	0	6	0	ð
5. Cats	Ó	O	Ö	0	0
6. Guinea Pigs	0	0	0	0	U
7. Hamsters	0	C	0	0	0
8. Rabbits	0	0	0	0	0
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	6	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	O	0	0	0	0
13. Other Animals	0	6	0	0	0
				·	

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual reset teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary incommendation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

	ATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL xecutive Officer or Legally Responsible Institutional Official)	
AL	NAME A TITLE OF A F.O. OR INOTITUTIONAL OFFICIAL (Time as Rend)	DATE SIGNED

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0119
CUSTOMER NUMBER: 16933

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Hybrizyme Corp. 2801 Blue Ridge Rd-Suite G70 Raleigh, NC 27607

Telephone: (999) -999-9999

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

NA

A.  Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, a	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to	F.  TOTAL NUMBER OF ANIMALS  (COLUMNS C+D+E)
4. Dogs					
5. Cats		·			
6. Guinea Pigs		18			18
7. Hamsters					
8. Rabbits					
9. Non-human Primate					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
		1	<del></del>		

#### ASSURANCE STATEMENTS

- 1). Professionally acceptable standards governing the care, treatment, and use of animals, including approriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, feaching, testing, surgery, or experimentation were followed by this research facility.
- 2). Each principal investigator has considered alternatives to painful procedures.
- 3). This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report in addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected:
- 4). The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTES RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
f certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

11/23/04

additional information

See attached form for U Introduction Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0120 CUSTOMER NUMBER: 20883

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Dynogen Pharmaceuticals 801 Capitola Drive Suite 12 Durham, NC 27713

Telephone: (919) -572-1919

3. REPORTING FACILITY ( List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary )

FACILITY LOCATIONS (Sites) - See Atached Listing

Same as above

REPORT OF ANIMALS	USED BY OR UNDER (	CONTROL OF RESEAR	CH FACILITY ( Attach addition:	al sheets if necessary or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analigesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for whithe use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, resor interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reask such drugs were not used must be attached to this report	OF ANIMALS  ( COLUMNS  C + D + E )
4. Dogs					
5. Cats	14		126	14	140
6. Guinea Pigs			141		141
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
ASSURANCE STATEMENT	·c	·			•

- Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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- action vetering right this research facility has appropriate authority to ensure the provision of adequate vetering years and to oversee the adequacy of other aspects of animal care and USE.

	TON BY HEADQUARTERS RESEARCH FACILITY OFFICIAL. ecutive Officer or Legally Responsible Institutional Official)	
SCOUNT OF OF OF OF OF WOTTH TOWN OFFICIAL	NAMER TITLE OF CEO. OR INSTITUTIONAL OFFICIAL (Two or Print)	DATE SIGNED

APHIS FORM 7023 ( AUG 91 )

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

((c))

## Column E Explanation

Date: 9/30/04

1. Registration Number: 55-R-0120

2. Number of animals used in this study: 14

3. Species (common name) of animal used in this study: cat

4. Explain the procedure producing pain and / or distress:

Surgical spinal cord injury at the lumbo-sacral region leading to paralysis of the lower extremities and bladder dysfunction.

5. Provide scientific justification why pain and / or distress could not be relieved. State methods or means used to determine that pain and / or distress relief would interfere with test results.

Dynogen is a privately held, neuroscience-based pharmaceutical company focused on genitourinary (GU) and gastrointestinal (GI) disorders. One of our focuses is on developing therapeutic treatments for paraplegic and quadriplegic patients with spinal cord injury. Spinal cord injury above the lumbo-sacral level disrupts control of urination. Urination in these patients ends up being involuntary or incomplete. Because of this the bladder often becomes overfilled, which can lead to disability or death due to kidney damage. Moveover, quadriplegic or paraplegic patients with spinal cord injuries at higher levels also can exhibit a dangerous condition called autonomic dysreflexia, in which dramatic and even life threatening elevation of blood pressure can be triggered by bladder distension. Through our experiments, we expect to identify drug treatments which will prevent the rises in bladder pressure, thereby preventing involuntary urination and bladder triggered life threatening episodes of autonomic dysreflexia.

Cats are often used in this model because, cats, like humans, have a bipartite control of micturiton wherein myelineated "A" delta fibers are predominately responsible for afferent signaling in the normal urination reflex. The rat uses a different pathway which is "C" fiber mediated and this has been shown to have responses of the bladder that are completely opposite of the cat and human (e.g., Kakizaki et al., Am J Physiol 280: 1407-13,2001). Due to the complex organization of the neurons within the nervous system and the distribution of various receptor types amongst those neurons, the experiments we conduct could not be replaced by computer modeling or in vitro techniques. The studies require the neurons to be interconnected exactly as they are in nature, which is only possible with an in vivo model such as we propose.

Great lengths have been taken to ensure these animals do not experience any pain and their distress level is minimal. Preoperative and postoperative analgesics are given to alleviate any pain they may experience at the site of the incision and the acute phase of the experiment which occurs 6-8 weeks post surgery, is performed under anesthesia. Long term dosing with analgesics is not indicated as the animals are not experiencing any pain and in fact would be detrimental as long term dosing has the potential for causing gastric upset and lethargy in the animal, which would impede recovery. Caging has been modified to include a padded floor and absorbant covering to ensure no bed sores develop and the animals remain clean and dry. One week post surgery these animals are let out for exercise and play time in a secured area just like the other cats in our facility. Although

they do not have control of their rear legs they do show the same exuberance to play with the enhancement toys offered, much like our other cats. Quality animal care is given to these cats, as to all our animals, seven days a week with Veterinary evaluation occuring once a week. Patient files are maintained in order to ensure the proper care is being documented and the health and the well being of the cats is monitored. In fact, once recovered from surgery these animals show so little signs of being distressed that collegues in other institutions have this same model filed under USDA category "D".

6. What, if any, federal regulation requires this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113. 102):
Not applicable.

NOV 1 7 2004 See attached form for

Interagency Report

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0121

> CUSTOMER NUMBER: 15523

FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Ardent Pharmaceuticals, Inc. 631 United Drive Durham, NC 27713

Telephone: (919) -806-1806

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY ( Attach additional sheets if necessary or use APHIS Form 7023A )					
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	( COLUMNS C + D + E )
4. Dogs					
5. Cats					
6. Guinea Pigs	3	24			24
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
ACCUIDANCE CTATEMENTO					

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) 1	The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of c	ther aspects of animal care and use.
	CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL ( Chief Executive Officer or Legally Responsible Institutional Official )	
SI	h is obsolete.)	DATE SIGNED

Interagency Report

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0122 CUSTOMER NUMBER: 22419

FORM APPROVED OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY** (TYPE OR PRINT)

Immunotherapeutics International IDCT 04 2004 730 Oakridge River Road Fuquay Varina, NC 27526

Telephone: (919) -539-3011

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

AT ABOUE ADDRESS ONLY

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS	USED BY OR UNDE	R CONTROL OF RESEAF	RCH FACILITY ( Attach additiona	al sheets if necessary or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not y used for such purposes.	animals upon which teaching, research, experiments, or tests were conducted	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C+D+E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters		1			
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
Goats	34	16			16
13. Other Animals					

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
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The attending veterinarian for this research facility has appropriate aut	hority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects	or animal care and use.
<del></del>	ON BY HEADQUARTERS RESEARCH FACILITY OFFICIAL cutive Officer or Legally Responsible Institutional Official)	
SIGNATURE OF CEA OF INSTITUTIONAL OFFICIAL	NAME & TITLE OF CEO OR INSTITUTIONAL OFFICIAL (Type or Print)	DATE SIGNED
•		30Sep 04

Interagency Report Control No.

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE 1. CERTIFICATE NUMBER: 55-R-0123

CUSTOMER NUMBER: 21633

FORM APPROVED OMB NO. 0579-0036

**ANNUAL REPORT OF RESEARCH FACILITY** 

(TYPE OR PRINT)

Synecor Lic

3908 Patrist Drive Sin + 170

- Po Box 14865-Research Triangle Pa, NC 27709

Duchan, NC

Telephone: (919) -541-9977

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS I	USED BY OR UNDER C	CONTROL OF RESEAR	CH FACILITY ( Attach additiona	al sheets if necessarv or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	F.  TOTAL NUMBER OF ANIMALS  ( COLUMNS C + D + E )
4. Dogs					
5. Cats				•	
6. Guinea Pigs				·	
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs	1	0	576	0	576
12. Other Farm Animals					
13. Other Animals					
		L			

## ASSURANCE STATEMENTS

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	CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL hief Executive Officer or Legally Responsible Institutional Official)	
SIGNATURE C	PART & TITLE OF O.C.O. OR INSTITUTIONAL OFFICIAL /Time or Dried	DATE SIGNED
	į	10.12.0
APHIS FORM 7	which is obsolete.)	

APHIS FORM 7

( AUG 91 )

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 55-R-0124 CUSTOMER NUMBER: 15718 FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Appalacian State University Appalachian State Univ Appalachian State University Boone, NC 28608

NOV 2 6 2004

Telephone: (704) -262-2130

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS L	USED BY OR UNDER C	CONTROL OF RESEAR	CH FACILITY ( Attach additiona	al sheets if necessarv or use APHIS Form 7023A )	
A.  Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use or pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reast such drugs were not used must be attached to this report	( COLUMN
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
clonys torridus	0	77	0	0	77
		<u> </u>			
ľ	1	<b>(</b>		1	1

# ASSURANCE STATEMENTS

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CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIA
(Chief Executive Officer or Legally Responsible Institutional Official.)

DATE SIGNED

11-22-04

APHIS FORM 7023

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)